JUN 1 1 2014

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K140425

Applicant Information:

Date Prepared: May 12, 2014

Name: Osprey Medical
Address: 5600 Rowland Rd, #250
Minnetonka, MN 55343
Phone: 952-955-8230
Fax: 952-955-8171

Contact Person: Melanie Hess, Sr. Director Regulatory Affairs
Phone Number: 952-955-8252
E-mail: mhess@ospreymed.com

Device Information:

Classification: II
CFR Reference: 870.1650 (product code DXT)
Trade Name: AVERT™ Contrast Modulation System
Common Name: Angiographic Injector
Classification Name: Angiographic Injector

Predicate Devices:

The proposed second generation AVERT™ (AVERT) Contrast Modulation System is substantially equivalent in intended use, method of operation and technical aspects to the first generation AVERT Contrast Modulation System (weighted) (K131478). The AVERT Contrast Modulation System is also similar to the Acist Angiographic Injection System (K993774, K991103, and K000013) and the Medline Angiographic Control Syringe (K093830).

Device	Reference 510(k) Number	Indication for Use
AVERT Contrast Modulation System (weighted)	K131478	… is intended to be used for the controlled infusion of radiopaque Iodixanol 270 mg/ml contrast media for angiographic procedures.
Acist Angiographic Injection System	K993774, K991103, K000013, and K052744	…intended to be used for the controlled infusion of radiopaque contrast media for angiographic procedures
Medline Angiographic Control Syringe	K093830	An angiographic syringe is a device that consists of a syringe which is used to inject contrast material into the heart, great vessels, and coronary arteries during angiographic or CT procedures.

Device Description:

Similar to the first generation AVERT Contrast Modulation System (weighted), the Osprey Medical second generation AVERT Contrast Modulation System consists of a reusable, non-sterile

apparatus (contrast modulator or RMS), which applies a force to a disposable modulation reservoir. The system also includes a wheeled stand for which to mount the RMS. The RMS applies a force directly to the single use sterile, detachable modulation reservoir, which has a pressure dampening effect during contrast delivery, similar to the weighted AVERT System. The RMS utilizes an internal mechanism to apply force to the modulation reservoir. The force can be easily and quickly adjusted by moving the location of the pin as identified on the outer housing of the system, thereby increasing or decreasing the amount of force applied to the modulation reservoir. The RMS is attached to the wheeled stand and is positioned near the patient, outside of the sterile field. The disposable components of the AVERT Contrast Modulation System include a modulation reservoir, which is connected to a standard, off-the-shelf 4-way stopcock and extension line that are all provided sterile.

Intended Use:
The AVERT™ Contrast Modulation System is intended to be used for the controlled infusion of radiopaque contrast media for angiographic procedures with the following agents: Iodixanol 270 or 320 mgI/ml, Iohexol 300 or 350 mgI/ml, and Iopamidol 370 mgI/ml.

Comparison to Predicate Device(s):
The AVERT Contrast Modulation System is substantially equivalent to the previously cleared AVERT Contrast Modulation System, K131478, in that they are both designed to control the infusion of radiopaque contrast media for angiographic procedures and function to reduce the users hand fatigue during routine angiographic procedures.

The AVERT Contrast Modulation System and previously cleared first generation weighted AVERT System both use an applied force that works to dampen the delivery of contrast media to a patient during an angiographic procedure. The AVERT Contrast Modulation System achieves this effect with an internal mechanism, which applies a force to the modulation reservoir. This applied force is easily adjustable by the user moving the location of a pin, whereas the weighted AVERT System achieved this by removing or adding individual weighted plates, placed in contact with the modulation reservoir. Whereas the Acist system is a powered injector adjusted via the user interface and the Medline syringe is manually controlled.

The above modifications allow the use of multiple commonly used contrast types. Design modifications to the modulation reservoir are also included specific to the second generation AVERT Contrast Modulation System.

The design of the AVERT Systems are comparable to the Acist Angiographic Injection System and the Medline Angiographic Control Syringe. The indication for use statement of the Acist Angiographic Injection System and the AVERT System are similar with the AVERT System having a more specific indication of contrast media type. The indication for use statement of the Medline Angiographic Control Syringe is similar in intention to the AVERT System.

Performance Data:
The AVERT Contrast Modulation System has been evaluated using the following *in vitro* bench testing to confirm the performance characteristics as compared to the predicate device:

- Flow Rate

- Peak Pressure Reduction
- Flow Rate Adjustability
- Mechanical Cycle Testing
- Distribution & Package Testing

All test results demonstrated that the materials, manufacturing processes and design of the Osprey Medical AVERT Contrast Modulation System met the established performance criteria and will perform as intended in a manner that is substantially equivalent to the predicate device.

In vivo testing was not deemed necessary based on the ability to evaluate the changes during bench testing and the insignificance of the modifications to the predicate device.

Biocompatibility tests were not deemed necessary, because there were no changes to any materials that are patient contacting. Therefore, biocompatibility testing conducted using the predicate device remains applicable to the proposed AVERT Contrast Modulation System.

Sterilization validation was conducted in accordance with ISO 11135 requirements for the single use modulation reservoir kit supplied with the RMS. The validation results indicated the components will be provided with a minimum sterility assurance level (SAL) of 10^{-6}.

Summary:
Based upon the intended use and descriptive information provided in this pre-market notification, the Osprey Medical AVERT Contrast Modulation System has been shown to be substantially equivalent to the currently marketed predicate device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 11, 2014

Osprey Medical Inc.
Ms. Melanie Hess
Sr. Director, Regulatory
5600 Rowland Road, Suite 250
Minnetonka, MA 55343

Re: K140425
Trade/Device Name: AVERT™ Contrast Modulation System
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: May 12, 2014
Received: May 13, 2014

Dear Ms. Hess:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

8. INDICATIONS FOR USE STATEMENT

510(k) Number: (TBA) K140425

Device Name: **AVERT™ Contrast Modulation System**

Indications For Use:

The AVERT™ Contrast Modulation System is intended to be used for the controlled infusion of radiopaque contrast media for angiographic procedures with the following agents: Iodixanol 270 or 320 mgI/ml, Iohexol 300 or 350 mgI/ml, and Iopamidol 370 mgI/ml.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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